# **Complete Summary**

#### **GUIDELINE TITLE**

Induction of labor.

## **BIBLIOGRAPHIC SOURCE(S)**

American College of Obstetricians and Gynecologists (ACOG). Induction of labor. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2009 Aug. 12 p. (ACOG practice bulletin; no. 107). [90 references]

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Induction of labor. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 1999 Nov. 10 p. (ACOG practice bulletin; no. 10). [70 references]

## **COMPLETE SUMMARY CONTENT**

SCOPE

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RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
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# **SCOPE**

## **DISEASE/CONDITION(S)**

## **Maternal and Fetal Conditions**

- Abruptio placentae
- Chorioamnionitis
- Fetal demise
- Gestational hypertension
- Preeclampsia, eclampsia

- Premature rupture of membranes
- Postterm pregnancy
- Maternal medical conditions (e.g., diabetes mellitus, renal disease, chronic pulmonary disease, chronic hypertension, antiphospholipid syndrome)
- Fetal compromise (e.g., severe fetal growth restriction, isoimmunization, oligohydramnios)

## **Other Conditions**

- Risk of rapid labor
- Distance from hospital
- Psychosocial indications

## **GUIDELINE CATEGORY**

Assessment of Therapeutic Effectiveness Counseling Evaluation Management Risk Assessment

## **CLINICAL SPECIALTY**

Obstetrics and Gynecology

## **INTENDED USERS**

Advanced Practice Nurses Physician Assistants Physicians

# **GUIDELINE OBJECTIVE(S)**

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review current methods for cervical ripening and induction of labor and to summarize the effectiveness of these approaches based on appropriately conducted outcomes-based research
- To classify the indications for and contraindications to induction of labor, describe the various agents used for cervical ripening, cite methods used to induce labor, and outline the requirements for the safe clinical use of the various methods of inducing labor

## **TARGET POPULATION**

Pregnant women requiring induction of labor

## INTERVENTIONS AND PRACTICES CONSIDERED

#### **Assessments**

- 1. Assessment of gestational age and consideration of potential risks to the mother or fetus
- Patient counseling regarding the indications for induction, the agents and methods of labor stimulation, and the possible need for repeat induction or cesarean delivery
- 3. Cervical and pelvic assessment and assessment of fetal size and presentation

## **Interventions**

- 1. Cervical ripening
  - Mechanical dilation methods including hygroscopic dilators, osmotic dilators (*Laminaria japonicum*), Foley catheters, double balloon devicesÂ
  - Administration of synthetic prostaglandin E<sub>1</sub> (PGE<sub>1</sub>, misoprostol) or prostaglandin E<sub>2</sub> (PGE<sub>2</sub>, dinoprostone)
- 2. Labor induction
  - Oxytocin, low or high dose regimens
  - Nonpharmacologic methods including stripping the amniotic membranes, amniotomy, and nipple stimulation
- 3. Continuous monitoring of uterine activity and fetal heart rate

## **MAJOR OUTCOMES CONSIDERED**

- Time to cervical ripening and labor induction
- Time to delivery
- Rate of uterine contraction after cervical ripening and labor induction
- Rate of maternal complications from various methods of cervical ripening and labor induction (e.g., tachysystole, membrane rupture, gastrointestinal side effects of drugs)
- Changes in fetal heart rate
- Degree of labor-associated pain
- Rates of vaginal delivery after labor induction

## **METHODOLOGY**

## METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

## **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and January 2009. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by

organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

#### NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

- I: Evidence obtained from at least one properly designed randomized controlled trial
- **II-1**: Evidence obtained from well-designed controlled trials without randomization
- **II-2**: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

# **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

# METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

#### **Levels of Recommendations**

- **Level A** Recommendations are based on good and consistent scientific evidence.
- **Level B** Recommendations are based on limited or inconsistent scientific evidence.
- **Level C** Recommendations are based primarily on consensus and expert opinion.

#### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

# **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

## **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

The grades of evidence (**I-III**) and levels of recommendations (**A-C**) are defined at the end of "Major Recommendations" field.

# The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

- Prostaglandin E analogues are effective for cervical ripening and inducing labor.
- Low- or high-dose oxytocin regimens are appropriate for women in whom induction of labor is indicated (see Table 2 in the original guideline document).

- Before 28 weeks of gestation, vaginal misoprostol appears to be the most efficient method of labor induction regardless of Bishop score, although highdose oxytocin infusion also is an acceptable choice.
- Approximately 25 micrograms of misoprostol should be considered as the initial dose for cervical ripening and labor induction. The frequency of administration should not be more than every 3–6 hours.
- Intravaginal prostaglandin E<sub>2</sub> (PGE<sub>2</sub>) for induction of labor in women with premature rupture of membranes appears to be safe and effective.
- The use of misoprostol in women with prior cesarean delivery or major uterine surgery has been associated with an increase in uterine rupture and, therefore, should be avoided in the third trimester.
- The Foley catheter is a reasonable and effective alternative for cervical ripening and inducing labor.

# The following recommendation is based on evidence that may be limited or inconsistent (Level B):

 Misoprostol (50 micrograms every 6 hours) to induce labor may be appropriate in some situations, although higher doses are associated with an increased risk of complications, including uterine tachysystole with fetal heart rate (FHR) decelerations.Â

#### **Definitions:**

#### **Grades of Evidence**

- I: Evidence obtained from at least one properly designed randomized controlled trial
- **II-1**: Evidence obtained from well-designed controlled trials without randomization
- **II-2**: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

#### **Levels of Recommendations**

- **Level A** Recommendations are based on good and consistent scientific evidence.
- **Level B** Recommendations are based on limited or inconsistent scientific evidence.
- Level~C Recommendations are based primarily on consensus and expert opinion.

# **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

Safe clinical use of various methods of inducing labor

## **POTENTIAL HARMS**

- The use of prostaglandins, oxytocin, and misoprostol is associated with an increased risk of tachysystole with or without fetal heart rate (FHR) changes.
   See the original guideline document for details of incidence.
- The use of misoprostol in women with prior cesarean delivery or major uterine surgery has been associated with an increase in uterine rupture and, therefore, should be avoided in the third trimester.
- Maternal side effects from the use of low-dose prostaglandin E<sub>2</sub> (PGE<sub>2</sub>) (fever, vomiting, and diarrhea) are quite uncommon.
- An increase in meconium-stained amniotic fluid has been reported with misoprostol use.
- The manufacturers recommend that caution be exercised when using PGE<sub>2</sub> in patients with glaucoma, severe hepatic or renal dysfunction, or asthma.
- Increased maternal and neonatal infections have been reported in connection with the use of *Laminaria japonicum* and hygroscopic dilators when compared with the PGE<sub>2</sub> analogues.
- The Foley catheter can cause significant vaginal bleeding in women with a low-lying placenta; as well as other reported complications such as rupture of membranes, febrile morbidity, and displacement of the presenting part.
- Uterine rupture secondary to oxytocin use is rare even in parous women.
- In patients after 28 weeks of gestation, cervical ripening with a transcervical Foley catheter has been associated with uterine rupture rates comparable to spontaneous labor.

## **CONTRAINDICATIONS**

# **CONTRAINDICATIONS**

The individual patient and clinical situation should be considered in determining when induction of labor is contraindicated. Generally, the contraindications to labor induction are the same as those for spontaneous labor and vaginal delivery.

Contraindications to labor induction include, but are not limited to, the following situations:

- Vasa previa or complete placenta previa
- Transverse fetal lie
- Umbilical cord prolapse
- Previous classical cesarean delivery
- Active genital herpes infection
- Previous myomectomy entering the endometrial cavity

# **QUALIFYING STATEMENTS**

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- These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.
- The majority of literature cited in this Practice Bulletin was published prior to the 2008 National Institute of Child Health and Human Development (NICHD) definitions and interpretations of fetal heart rate tracings (FHR).
   Consequently, it is difficult to generalize the results of the cited literature, which used nonstandardized and ambiguous definitions for FHR patterns.

## **IMPLEMENTATION OF THE GUIDELINE**

#### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

## **IMPLEMENTATION TOOLS**

Audit Criteria/Indicators Foreign Language Translations Patient Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

# **IOM CARE NEED**

Getting Better Staying Healthy

## **IOM DOMAIN**

# IDENTIFYING INFORMATION AND AVAILABILITY

# **BIBLIOGRAPHIC SOURCE(S)**

American College of Obstetricians and Gynecologists (ACOG). Induction of labor. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2009 Aug. 12 p. (ACOG practice bulletin; no. 107). [90 references]

## **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### **DATE RELEASED**

1999 Nov (revised 2009 Aug)

## **GUIDELINE DEVELOPER(S)**

American College of Obstetricians and Gynecologists - Medical Specialty Society

## **SOURCE(S) OF FUNDING**

American College of Obstetricians and Gynecologists (ACOG)

## **GUIDELINE COMMITTEE**

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Obstetrics

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

American College of Obstetricians and Gynecologists (ACOG) committees are created or abolished and their overall function defined by the Executive Board. Appointments are made for one year, with the understanding that such appointment may be continued for a total of three years. The majority of committee members are Fellows, but Junior Fellows also are eligible for appointment. Some committees may have representatives from other organizations when this is particularly appropriate to committee activities. The president elect appoints committee members annually.

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

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## **GUIDELINE AVAILABILITY**

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: <a href="mailto:sales@acog.org">sales@acog.org</a>. The ACOG Bookstore is available online at the <a href="mailto:ACOG Web site">ACOG Web site</a>.

## **AVAILABILITY OF COMPANION DOCUMENTS**

Proposed performance measures are included in the original guideline document.

#### **PATIENT RESOURCES**

The following is available:

 Labor induction. American College of Obstetricians and Gynecologists (ACOG); 2009.

Available from the <u>American College of Obstetricians and Gynecologists (ACOG)</u> Web site. Copies are also available in Spanish.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; <a href="mailto:e-mailto

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# **NGC STATUS**

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